

# Double-sided back muscle numbing for pain relief pain after having the gallbladder removed using keyhole surgery

<b>Submission date</b> 16/09/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/09/2023	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Laparoscopic cholecystectomy is a specific type of surgery where the gallbladder is removed using small incisions and a camera. An erector spinae block is a medical procedure in which a local anesthetic (a medication that numbs sensation) is injected near the erector spinae muscles along the spine. This is done to block or numb the nerves that transmit pain signals from the surgical area to the brain. The purpose of using this block is to provide effective pain relief during and after the surgery. By numbing the nerves in the area, it helps reduce the amount of pain the patient feels, making the surgical procedure more comfortable and improving the postoperative recovery experience. It's a part of the overall pain management strategy for the surgery, potentially leading to better pain control and a smoother recovery process for the patient.

### Who can participate?

Patients getting laparoscopic cholecystectomy

### What does the study involve?

Patients were split into two groups: one receiving general anesthesia plus regular pain control, and the other receiving both of those plus an erector spinae block.

### What are the possible benefits and risks of participating?

The potential advantages include better pain relief, while the risks involve the use of ultrasound to guide the block.

### Where is the study run from?

Universidad del Sinu (Colombia)

### When is the study starting and how long is it expected to run for?

May 2021 to February 2023

Who is funding the study?  
Universidad del Sinu (Colombia)

Who is the main contact?  
Mauro Causil, jjmoralesb@unal.edu.co

## Contact information

### Type(s)

Principal investigator

### Contact name

Mr Mauro Causil

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

08012021

## Study information

### Scientific Title

Bilateral erector spinae block for postoperative analgesia in laparoscopic cholecystectomy: A randomized clinical trial

### Study objectives

ESPB improves postoperative analgesia and reduces opioid consumption

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 08/01/2021, Clinica La Concepcion Ethics Committee (CALLE 38 52 249 LOS ALPES, Sincelejo, 700001, Colombia; (+57) 5 2749180; info@laconcepcion.org), ref: 08012021

**Study design**

Prospective interventional randomized clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Improvement of analgesia in patients undergoing laparoscopic cholecystectomy

**Interventions**

There were 2 study arms: one was general anaesthesia + standard analgesia and the other arm was general anaesthesia + standard analgesia + bilateral US-guided erector spinae block. Follow up was 48 hrs after surgery to record pain scores. The randomization process was done using Epi Dat 4.2.

**Intervention Type**

Other

**Primary outcome(s)**

Pain measured using a 0 (least)-10 (worst) pain score 1, 6, 12, 24 and 48 hr after surgery

**Key secondary outcome(s)**

Requirement of opioid (Yes or No) 1 hour after surgery

**Completion date**

28/02/2023

**Eligibility****Key inclusion criteria**

1. More than 18 years old
2. ASA I,II
3. Undergoing laparoscopic cholecystectomy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

68

**Key exclusion criteria**

1. IMC >30
2. Open cholecystectomy
3. Allergy to local anesthetics
4. Recent opioid use

**Date of first enrolment**

01/08/2021

**Date of final enrolment**

28/02/2023

## **Locations**

**Countries of recruitment**

Colombia

**Study participating centre**

Clinica La Concepcion

CALLE 38 52 249 LOS ALPES

Sincelejo

Colombia

700001

## **Sponsor information**

**Organisation**

Universidad del Sinú

**ROR**

<https://ror.org/013ys5k90>

## **Funder(s)**

**Funder type**

University/education

## Funder Name

Universidad del Sinú

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and or analyses during the current study will be available upon request from [jjmoralesb@unal.edu.co](mailto:jjmoralesb@unal.edu.co)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes